

**REMARKS**

With this Amendment, claims 1-14 are pending in the present application. Claims 1 and 11 have been amended.

**I. Summary of Examiner Interview**

Applicant would like to thank Examiner Cumberledge and Examiner Robert for the interview extended to Applicant's counsel of record, Richard Kim and Kaare Larson, on August 30, 2006. During the interview, the Examiner's § 112, first paragraph rejection was discussed. In particular, the Examiners questioned whether adding grooves and/or tunnels to a solid metal rod can provide flexibility to the metal rod. In response, Applicant's counsel commented that solid metal rods with grooves cut or formed into them can be flexible and their flexibility will depend on factors such as the type of material of the rod, the thickness of the rod, the depth and width of the grooves in the rod and the diameter and placement of holes in a rod. No resolution was reached during the interview on this point and the Examiners requested that Applicant submit its arguments formally in writing. Accordingly, Applicant submits the present Response to the pending Office Action.

**II. Rejection Under 35 U.S.C. § 112, First Paragraph**

The Examiner objected to the specification and claims of the present application under 35 U.S.C. § 112, first paragraph.

**A. Specification**

The Examiner objected to the specification under the first paragraph of 35 U.S.C. § 112 alleging that the specification fails to provide an adequate written description of the invention and fails to adequately teach how to make and/or use the invention. Specifically, the Examiner alleged that "[i]t is unclear from the applicant's disclosure how a solid metal rod (claim 1) made of titanium, stainless steel, titanium, titanium alloy, and/or NITINOL (claim 2) can acquire a flexible property by adding grooves (claim 1) and tunnels (claim 6) to the metal."

Applicant respectfully traverses this objection. First, Applicant submits that a solid metal rod can be flexible and its flexibility will be affected, for example, by its material composition and dimensions (e.g., length, width, thickness, etc.). Moreover, adding grooves and/or tunnels to the metal rod will increase the flexibility of the rod. As noted above, the degree of flexibility can depend upon a number of factors, including the material composition and thickness of the rod, as well as the depth, width and placement of grooves and/or tunnels in the rod. Specific examples of types of metal and sizes and configurations of grooves and tunnels that provide flexibility to metal rods used as flexible connection units for spinal stabilization are disclosed in the present application, such as the embodiments depicted in Figures 36-40 and the associated written description of those figures.

Thus, Applicant submits that the present application provides more than adequate support in the specification to “clearly convey the information that [the] applicant has invented the subject matter which is claimed.” *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977) (describing the “essential goal” of the written description requirement is to convey that the applicant has invented the subject matter which is claimed). Moreover, Applicant’s disclosure meets the enablement provisions by, among other things, providing specific examples of how to make and use such flexible connection units, as disclosed in figures 36-40 and the associated written description of those figures.

Applicant also notes that in order to make a lack of enablement rejection, an examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *See In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also* MPEP § 2164.01. As stated by the court, “it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ at 370 (emphasis added). In the present Office Action, however, Applicant respectfully submits the Examiner did not satisfy this

initial burden. Specifically, the Examiner did not provide any evidence as to why a solid metal rod cannot acquire additional flexibility by adding grooves and tunnels to the rod. The Examiner relies instead on the statement: “[i]t appears that the metals (especially titanium and steel) would not acquire any significant flexibility from adding grooves and holes in them.” This is merely a speculative statement and does not provide any evidence as to why Applicant’s disclosure is inaccurate or incomplete. Thus, in the event the Examiner decides to maintain this rejection, Applicant respectfully requests that the Examiner provide specific evidence as to why adding grooves or tunnels to a solid metal rod cannot provide flexibility to the rod.

In view of the above, Applicant respectfully requests withdrawal of the § 112, first paragraph objection to the specification.

#### **B. Claims**

The Examiner rejected claims 1-14 under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification. Applicant respectfully requests that this rejection be withdrawn because the specification adequately discloses how one skilled in the art could make and/or use the invention defined by claims 1-14, as set forth above with respect the response to the Examiner’s objection to the specification.

The Examiner also objected to claims 1-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically, the Examiner noted that there is insufficient antecedent basis for the limitation “rod” in claim 1. In response, Applicant has amended the objected to term “rod” to “the rod” in claim 1. Accordingly, Applicant respectfully submits that this rejection be withdrawn.

#### **III. Rejection Under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1, 2, 6-9 and 11-13 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,447,546 to Bramlet (the “546 Patent”). Applicant

believes the Examiner mistakenly cited the incorrect patent, as the Examiner's cited description and figures do not correspond to the '546 Patent. Instead, it is believed that the Examiner intended to cite U.S. Patent No. 6,475,242 to Bramlet (the "'242 Patent") as the basis for this rejection. Thus, Applicant will address this rejection in view of the '242 Patent.

Applicant respectfully disagrees with the Examiner's position that Bramlet discloses each of the limitations of claim 1 and claim 11. However, for the purpose of expediting the present application to issuance, Applicant has amended independent claims 1 and 11 to include a further limitation not disclosed by Bramlet. Specifically, claims 1 and 11 now recite a "connection unit having a first portion configured to be coupled to a first securing member and a second portion configured to be coupled to a second securing member." Support for this additional limitation is found in Applicant's specification at, for example, paragraph [0120]. Bramlet does not disclose or suggest a connection unit having grooves (claim 1) or tunnels (claim 11) that is configured to be coupled to first and second securing members. Accordingly, Applicant respectfully requests withdrawal of Examiner's rejection of claims 1 and 11 as being anticipated by Bramlet.

#### **IV. Rejection Under 35 U.S.C. § 103**

The Examiner rejected claim 1-14 under 35 U.S.C. § 103 as being unpatentable over the '546 Patent. As discussed above, Applicant believes that the Examiner mistakenly cited the '546 Patent instead of the '242 Patent ("Bramlet"). Accordingly, Applicant will address this rejection in view of the Bramlet.

As discussed above with respect to the § 102 rejection, Bramlet does not disclose or suggest each and every limitation of independent claim 1 or 11, as amended. In particular, Bramlet neither discloses nor suggests a connection unit having grooves (claim 1) or tunnels (claim 11) and having "a first portion configured to be coupled to a first securing member and a second portion configured to be coupled to a second securing member," as now recited in amended claims 1 and 11. Accordingly, Applicant submits that claims 1 and 11, as amended, are not obvious in view of Bramlet. Applicant respectfully requests the Examiner to withdraw this rejection.

**V. Dependant Claims**

Claims 2-10 and 12-14, which depend upon claims 1 and 11, respectively, recite additional features of particular advantage and utility. Moreover, these claims are allowable for at least the same reasons presented above. Thus, Applicant respectfully requests that the Examiner withdraw the § 102 and §103 rejections of these claims.

**VI. Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 559552000120. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 31, 2007

Respectfully submitted,

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